PHOENIX
TRANSLATIONS

September 30, 2008

Re: German Patent No. DE 39 35 906 C2

To Whom It May Concern:

This is to certify that the above-referenced document (.pdf file "106 18329_ DE03935906C2") has been translated from German into English by a professional translator on our staff who is skilled in the German language.

The attached English translation conforms essentially to the original German except for those words or phrases for which there are no equivalents. Such words or phrases are noted in the translation along with the best English meaning.

Rene Rosales

Subscribed and sworn to before me on September 30, 2008.

Charles Wilkinson
Notary Public, State of Texas

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My Commission Expires
January 05, 2011

My commission expires: January 05, 2011

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(56) Documents taken into consideration for the evaluation of patentability:
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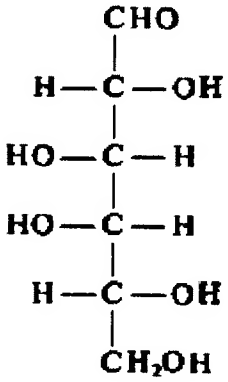
SPARKS, John W. et al.: Parenteral galactose therapy in the glucose-intolerant premature infant. in: J. Pediatr. 1982, pp. 225-9;
INQUE, T.: Studies of intravenous galactose tolerance test on various diseases, 1st abstract in: Biological Abstracts 64 (1977), 19641;

(54) USE OF GALACTOSE FOR PARENTERAL NUTRITION AND TREATMENT OF PATIENTS

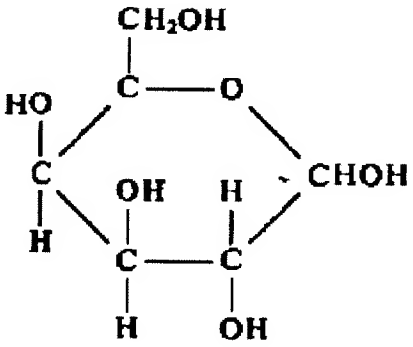
Description

The invention relates to the use of galactose (galactose) for the parenteral nutrition and treatment of patients who require intensive care (i.e., in intensive care medicine) or who are under metabolic stress, in the form of appropriate preparations that contain monosaccharides, of which at least a significant portion consists of galactose (D galactose).

Galactose (which refers generally to "D galactose" because this is the natural physiological form of occurrence of this sugar) represents, as is known, an aldohexose isomer of D-glucose, which occurs bound to lactose in lactic sugar, and in some rubber types in the form of galactans. Galactose has the following formula



or as pyranose



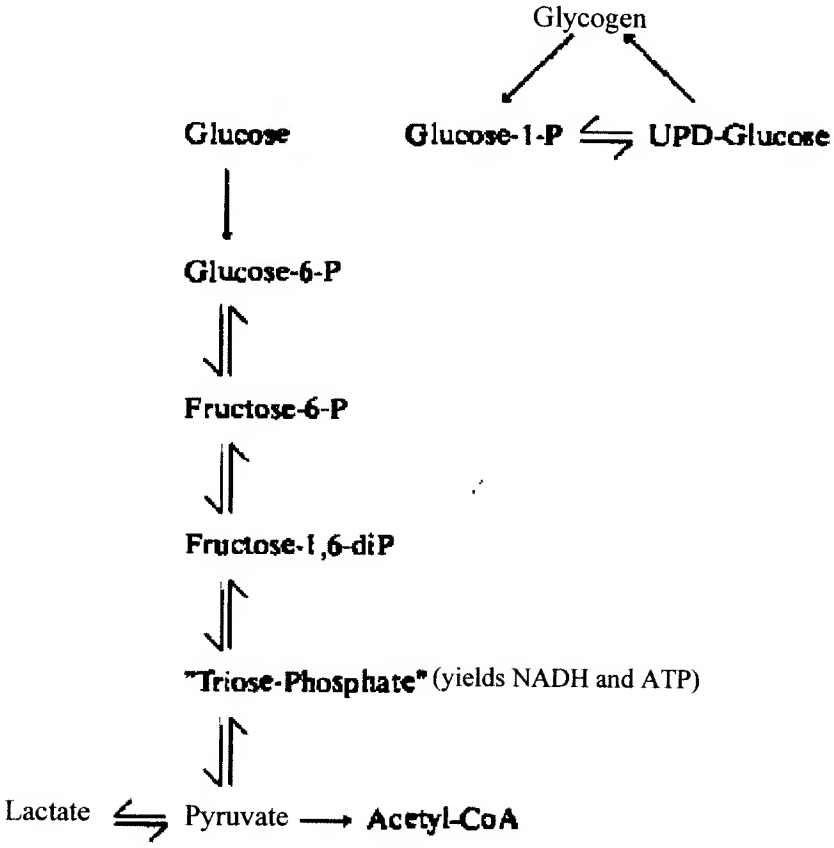
A derivative of galactose (D galactose) is fucose, i.e., 6-deoxygalactose, whose L form is the more important isomer form. Other derivatives are D galactoside and D galactosamine, i.e., 2-amino-2-deoxy derivatives of D galactose. In the case of galacturonic acid, the C_6 carbon atom is oxidized to the carboxyl group.

The parenteral nutrition and treatment of patients in a medical intensive care station concerns primarily patients who are in a pronounced metabolic stress situation. To date, attempts have been made to cover the required energy need with glucose and amino acid mixtures. Because every cell needs primary energy in the form of ATP for this function, the substrates of the infusion solutions are used for the production of this energy-rich compound.

Several preparations in the form of carbohydrate infusion solutions that contain glucose or fructose are available commercially, for example, Fructosteril®, the Braun® Glucose Infusion Set, Salvia® glucose solutions, the Glucose Solution Biotest, and Glucosteril®. Besides a monosaccharide, these preparations in many instances contain special nutrient salt combinations, to ensure isotonicity as well. Combination solutions with special amino acids or protein hydrolysates contain primarily the monosaccharides D glucose and D fructose, whereas several other infusion and standard injection solutions contain primarily sorbitol and inositol. To date,

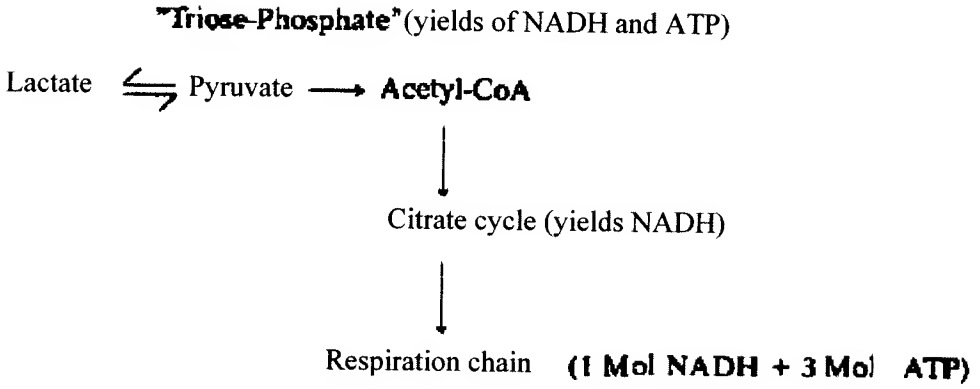
galactose has not been used for these purposes. Rather, glucose so far has been considered to be particularly appropriate for these purposes, because it yields, during glycolysis, corresponding energy equivalents in the form of NADH. The electrons that are present in the NADH formed serve in the respiration chain for ATP formation, as shown in the following reaction scheme 1.

Reaction scheme 1



The final product of D glucose respiration in aerobic glycolysis is pyruvate (pyruvic acid). For this purpose, mitochondrial acetyl coenzyme A is formed, which sets the citrate cycle in motion, and thus starts the formation of additional NADH molecules, 3 mol NADH per mol acetyl CoA. Subsequently, in the respiration chain, 3 mol of ADP are formed from 1 mol NADH (see the following reaction scheme 2).

Reaction scheme 2



In total, for each mol of metabolizable glucose, 36 mol ATP are formed. Expressed in units of weight, 82 g ATP are formed from 1 g glucose. Because of the greater need for ATP, the cell must convert, rapidly and to the extent possible quantitatively, glucose into pyruvate and acetyl coenzyme A for the citrate cycle. Because the glucose of the infusion solution as a rule is not sufficient for this purpose, a portion of the infused amino acid, for example, glutamic acid, aspartic acid, proline, glycine or lactate is converted into D-glucose, which again feeds the glycolysis, i.e., the pyruvate formation with all the subsequent steps for the formation of NADH. Because the first goal of a cell is to have available sufficient ATP in a metabolic stress situation to maintain life sustaining functions, a considerable portion of the amino acids also contributes to energy production via gluconeogenesis.

As a result of this primary status of energy metabolism, anabolism reaches a state of deficiency. This particularly affects the oligosaccharide portions of proteins and lipids, i.e., the glycoproteins and glycolipids (for example, gangliosides). They participate in numerous essential cell functions, which start from membranes or are located in membranes. Thus, all the receptors of a cell belong to this complex group: receptors for hormones, for growth factors, and for cell-cell contact. They are the antennas of a cell, without which a cell would perish in the long run.

Glycoproteins are also important as membrane bound enzymes and transport systems: They represent the antigenicity of a cell. In summary, they regulate the information reception and transmission of a cell and moreover they are responsible for each cell's characteristic biochemical and morphological appearance. The substrates required are formed via side paths of glycolysis. The primary substrate in each case is a metabolite of glucose in glycolysis (see diagram), for example, glucose-6-P or fructose-6-P.

1. From glucose-6-P, UDP glucose is formed via glucose-1-P, from which the essential glycoprotein and glycolipid substrate UDP-galactose is formed by epimerization.

2. From fructose-6-phosphate, the following are formed:

a) by amidation, glucosamine-6-phosphate, the substrate for the formation of the activated amino sugars:

- UDP-N-acetylglucosamine
- UDP-N-acetylgalactosamine and
- CMP-N-acetylneuraminic acid

b) by epimerization:

mannose-6-phosphate, the substrate for GDP-mannose and

GDP-L-fucose

Fructose should not be used as an infusion substrate for that purpose because of the known side effects. They are associated with rapid phosphorylation and the associated ATP waste in the cell, followed by the degradation to uric acid of the AMP produced.

To ensure the supply of the anabolism in patients with a metabolic deficit, it would be desirable to have an infusion solution which, instead of, or in addition to D-glucose, infuses an anabolic substance by means of which the disturbance of the essential functions of receptors or transport systems of the metabolism can be rapidly corrected.

From GB Patent 20 90 115, nutrient compositions are known which are administered enterally or orally to patients before or after surgery. They contain lactose, which is cleaved in the gastrointestinal tract by the lactase contained in it into glucose and galactose. This also applies to the infusion solutions that are known from the "Grüne Liste 1989, Aulendorf: Editio Cantor," which contain lactose and are administered orally or enterally.

The parenteral administration of galactose to date is known only from the paper by John W. Sparks et al., "Parenteral galactose therapy in the glucose-intolerant premature infant," printed in "J. Pediatr." 1982, pp. 255-259. According to this paper, galactose is administered parenterally to premature babies who suffer from glucose intolerance. Here, hyperglycemic conditions occur in the neonates, which are combated by parenteral galactose administrations. The paper makes no mention of either the treatment of hypoglycemic states in patients in intensive care medicine, particularly in the preoperative and the postoperative phase, by the administration of galactose, nor the treatment of liver diseases, absorption disorders, Alzheimer's disease, or diabetes mellitus with galactose.

The problem of the invention was to find a construction component, by means of which the disorders of the essential functions of receptors or transport systems of the metabolism can be rapidly corrected.

The object of the invention is the administration of galactose in the form of infusion and injection preparations for parenteral (i.e., intravenous, subcutaneous or intramuscular) administration on the basis of monosaccharides, which, in addition to galactose, contain

optionally essential amino acids, supplementing proteins, inorganic electrolytes, as well as the usual dilution, pH regulation, stabilization and preservative additives, in which at least 5 wt%, preferably at least 10 wt%, and particularly preferably at least 20 wt% of the monosaccharide contain at least 50 mol%, preferably 100 mol% galactose, where any remainder comprises the following compounds: L-fucose, D-mannose, D-glucosamine, N-acetylgalactosamine, N-acetylmannosamine, and mixtures thereof.

It is particularly preferred to use galactose in a glucose preparation of the usual composition, in which 50 to 100% of the D-glucose is replaced with galactose (D-galactose).

In the use according to the invention of galactose in the form of infusion and injection preparations for parenteral administration, galactose and D-mannose are preferably present in a molar ratio in the range from 200:1 to 2:1, galactose and D-glucosamine are preferably present in a molar ratio in the range from 200:1 to 2:1, galactose and N-acetylmannosamine are present preferably in a molar ratio in the range from 10:1 to 2:1, and galactose and L-fucose are present preferably in a molar ratio in the range from 200:1 to 2:1.

In the use according to the invention of galactose in the form of infusion and injection preparations for parenteral administration, D-mannose and D-glucosamine are present preferably in a molar ratio from 10:1 to 1:10.

As amino acids, such infusion and injection preparations can contain arginine, phenylalanine, valine, leucine, isoleucine, lysine, methionine, histidine, threonine and/or tryptophan in a quantity of in each case corresponding to 0.5-10 g per liter of respectively injection solution. In addition, they can contain dextran or hydroxyethyl starch in a quantity of up to 75 g/L and/or, as protein, albumin in a quantity of up to 60 g/L. They can also contain, as electrolytes, a source for sodium, potassium, calcium and magnesium ion in a total quantity of up to 200 mval/L solution, where the ratio between the monovalent and the bivalent electrolyte ions is preferably in the range from 35:1 to 10:1.

As electrolyte anions, such preparations contain primarily organic anions and preferably salts of D-galactonic acid and of D-galacturonic acid. Infusion and injection preparations that are particularly preferred for parenteral administration contain D-glucose and/or D-fructose as additional monosaccharide, besides galactose.

It has been found that up to 50 mol% of the above-mentioned representative can consist of another monosaccharide besides D-galactose, although more than 75 mol% D-galactose is preferred. Pure D-galactose preparations are particularly preferred.

Besides the monosaccharides (a), the above-mentioned preparations according to the invention can in addition contain essential amino acids (b), preferably in a quantity of 1-15 g/L for each amino acid, where the following representatives are particularly preferred: arginine, phenylalanine, valine, leucine, isoleucine, lysine, methionine, histidine, threonine, tryptophan,

cystine, and cysteine, all in the L form. Of the above-mentioned amino acids, arginine, phenylalanine, valine, leucine, isoleucine, lysine, and methionine are particularly preferred.

Specifically, essential amino acids with the following preferred quantitative proportions are present: arginine (1-8 g/L), phenylalanine (2-9 g/L), valine (1-7 g/L), leucine (2-9 g/L), isoleucine (1-8 g/L), lysine (2-9 g/L), methionine (2-6 g/L), histidine (1-5 g/L), threonine (1-6 g/L) and tryptophan (0.5-2.5 g/L).

In many instances, the amino acid proportion is combined with the hydrocarbon portion only in the final solution. However, powdered and other prefinished packaging forms are also possible.

Another possible component of the preparations according to the invention consists of supplementing proteins, which complement the nutritional needs of a patient who is suffering from stress. γ-Globulins and albumins, such as γ-globulin from Cohn fractions II, III and IV of guinea pigs, chickens, dogs, horses, rabbits, sheep and goats, lactalbumin, oval albumin, and serum albumin are particularly preferred. Preparations of this group are available commercially, for example, as γ-Venin® and Humanalbumin® or Humanalbumin Biotest 5%®.

The preferred quantity of the proteins is in the range from 2.5 to 10 g/L solution. Besides the above-mentioned proteins, other water-soluble proteins can also be added. The albumin quantity is generally slightly larger and it corresponds to 2.5 to 10% of the finished infusion or injection solution.

Complex compounded galactose preparations generally also contain electrolytes, such as, sodium chloride, potassium chloride, calcium chloride, and magnesium chloride (7 H_2O, where the ratio of the monovalent cations to the bivalent cations is generally preferably in the range from 35:1 to 10:1. The alkaline cation is made available primarily by sodium.

In addition, finished preparations contain water and optionally a buffer, such as sodium hydrogen phosphate and sodium acetate. Optionally, plasma diluents can also be obtained as blood substitutes, for example, dextran in a quantity of preferably 40-75 g/L, such as, "4% Dextran 40E®", "6% Dextran 60®", "Dextran 40®", "60®", "75®" or poly(0.2-hydroxyethyl) starch in a quantity of 40-75 g/L, such as, for example, Plasmasteril®.

If the solution contains plasma expanders, the albumin can be omitted. Up to 60 g/L albumin are otherwise appropriate. γ-Globulin and albumin are usually injected only during or shortly before the administration of the infusion solution. Galactose can also be added to a known injection solution, or infusion solution by injection, shortly before the administration.

The preparations that have been produced according to the invention can be in a solid form or in the form of a solution, and, before the administration, they are dissolved or diluted to the correct dilution. Thus, for the production of the preparations, ampules with a 50% galactose solution can be used.

The preparations can also be made as a syrup. As a rule, a concentrated galactose solution from an ampule is mixed with a standard infusion solution or injection solution.

The admixing usually occurs during the manufacture of the final infusion solution, in order to adjust the above-indicated concentration values. A 1 to 10% solution presents suitable galactose concentrations. In a given case, the glucose concentration can reach 10 to 0%. The preparations used in the following examples correspond to 5% galactose in a base electrolyte infusion solution with or without additional components.

The preparations produced according to the invention are suitable for the treatment of all forms of metabolic stress, particularly during hepatic coma patients, and in other intensive care unit patients who must receive parenteral nutrition, for example, after serious operations, accidents, in cases of chronic wasting diseases or adsorption disorders such as extensive inflammatory intestinal diseases or extensive small intestine resections. A special field of application exists in stress situations in the case of diabetes mellitus, for example in hypoglycemic states. Interestingly, the hemoglobin-bound glucose values were successfully reduced again with galactose administration, relatively rapidly, to return to the normal level, if a lapse is observable (HbA_1 and HbA_1 C values); this can be explained directly by the biochemical substitution effect of galactose, although the intention here is not to settle on any particular theory.

An additional administration variant consists in combating the symptoms of Alzheimer's disease. In Alzheimer's disease, glucose consumption in the brain is increased, as reported recently at the Alzheimer's meeting in Berlin 1989. The brain is subjected here to a potential substrate deficit for glycolipids (gangliosides) and glycoproteins, which can be corrected by galactose administrations. It has been found that the strictly glucose-dependent brain can here be supplied well with galactose.

In general, the preparations made according to the invention can be used for various skull-brain traumas, such as, stroke, cerebral concussions, and other metabolically caused diseases.

After the parenteral administration of D-galactose (800 mg/kg), there is as expected, an increase in UDP galactose level by a factor of 2-3; the level of UDP glucose, which can form directly from UDP galactose, also increases, although not as drastically. Subsequently, galactose, to the extent that it is not used for the glycan synthesis (of glycoproteins, glycolipids), is converted partially into amino acids. The conversion of glutamic acid and gamma aminobutyric acid (GABA) is here clearly measurable, particularly in the brain. Both serve neurotransmitter functions in the healthy brain. The quantity of glutamate formed in the brain reaches up to 2 µmol/g fresh weight, that of GABA up to 0.3 µmol/g (normal values: 8.7 and 2.3 µmol/g, respectively).

In comparison to the main metabolic organ, the liver, the brain is characterized according to this finding in a particular way. The glutamate and GABA synthesis is improved according to the invention; both substances are essential for brain function, which in "intensive care unit" patients and Alzheimer's disease patients is usually restricted. At the same time, this achieves consumption of amino groups. Thus, this medication functions simultaneously in detoxification, because these amino groups are a precursor of ammonia. Ammonia is produced in large quantities, particularly in liver comas, and it leads to severe impairments of the cerebral functions (encephalopathies). The administration of galactose can thus contribute to the detoxification.

It has been found that by infusing D-galactose-containing solutions, a rapid and noticeable recovery of the patient occurs, which is not the case with the glucose-containing solutions available to date. A possible explanation for this observation could be the following.

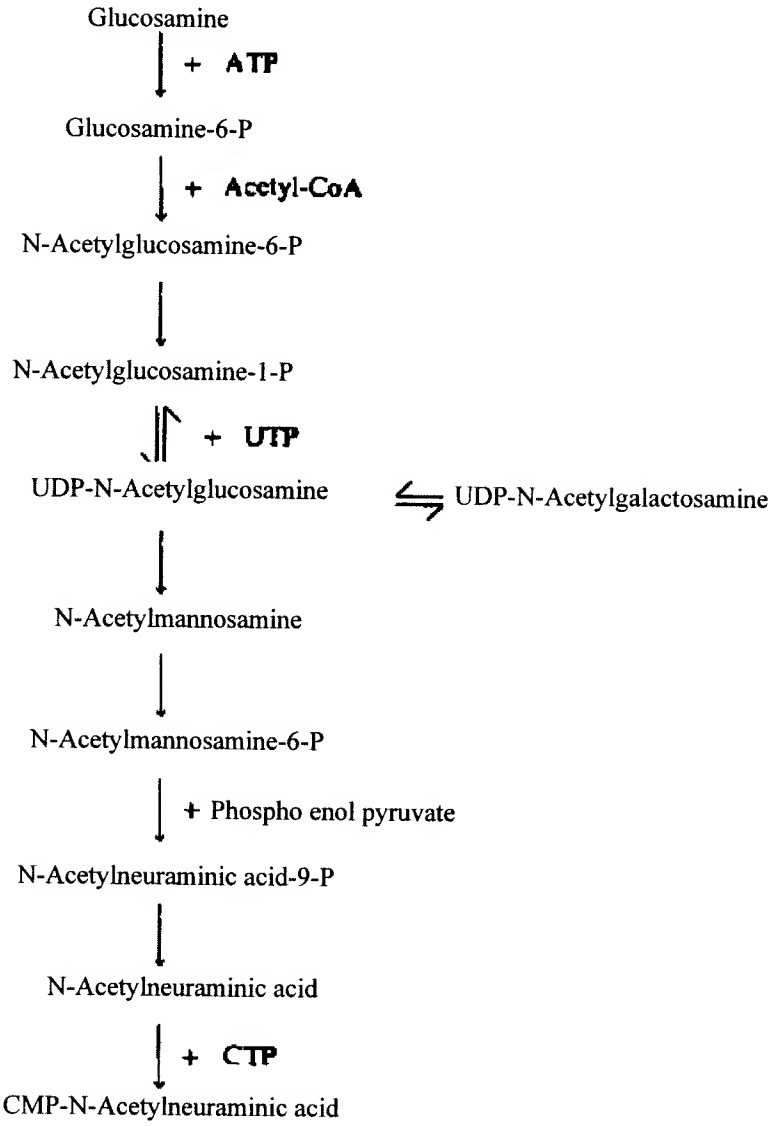
The enzymes of the anabolism are understandably less active than those of the energy producing metabolism. Therefore, a substrate deficit in the biosynthesis of glycoproteins or glycolipids manifests itself only later as an energy deficit. However, the consequence then is that disorders of the central functions of receptors or transport systems occur. If, for example, the insulin receptor, a glycoprotein, becomes defective as a result of insufficient glycosylation, then insulin can no longer be recognized by the cell, and it can no longer exercise its function to a sufficient degree. This applies to all hormones or regulators that require binding to a membrane receptor to initiate their function.

If one now adds to the infusion solutions an additive of essential substrates for the anabolism, primarily D-galactose and/or D-glucosamine, then an immediate activation of the anabolism occurs.

D-Galactose is converted very rapidly, via D-galactose-1-phosphate, into UDP-D-galactose; this formation does not occur via UDP glucose. Excess UDP galactose, however, can be introduced via UDP glucose (by epimerization) into the glycolysis. However above all, sufficient UDP galactose for the anabolism is available.

The situation is similar with D-glucosamine. This amino sugar is converted in the cell, also after phosphorylation, into activated amino sugars, which are needed for biosynthesis, namely UDP-N-acetylglucosamine, the epimer UDP-N-acetylgalactosamine, and after several steps, CMP-N-acetylneuraminic acid. The following scheme clarifies this.

Reaction scheme 3



The activated D-mannose, and L-fucose compound which can be derived from the former compound, occur in the organism at a lower concentration than the UDP sugars. It is possible that the endogenous formation from fructose-6-phosphate or reutilization is enough to maintain sufficient concentrations.

It is extraordinarily advantageous to replace an infusion solution with galactose, for example, as a 1% solution. There is no risk of cataract formation. In rats, it occurs only after 3 to 4 weeks, if total nutrition consists of up to 40% galactose.

The use of galactose in patients in a metabolic stress situation appears advantageous for an additional reason. Excess D-galactose is converted very well into amino acids. For this

purpose, the corresponding intermediates have to be aminated. Galactose therefore helps in reducing the use of nonessential amino acids in infusion solutions.

In addition, for patients with hepatic coma, the use of galactose restricts ammonia formation by making the amino groups necessary for the required transaminations. The galactose is assigned a "protein saving effect," which is presumably based on this characteristic.

Example 1

For the preparation of a D-galactose preparation that can be used according to the invention, pure D-galactose was used to make a concentrated solution, optionally together with additional compounds of the above-mentioned monosaccharides. This galactose base composition is then admixed via dilution to a known standard or special infusion solution, where the desired final concentration is set in accordance with a 1 to 10% concentration of D-galactose. The infused or injected solutions are compounded in such a way that approximately 100-800 mg/kg are administered parenterally per day to a human patient. It was found that galactose administration, with same effect, is clearly lower than a corresponding administration of D-glucose, which can be seen particularly impressively using a concentration series of galactose/glucose, if the galactose concentration increases steadily. At least 5% of the monosaccharides should be made available by a monosaccharide of the above-mentioned group. In the following table, several special preparations are recorded, which at the same time are representatives of preferred preparations. Galactose can serve as a glucose supplement for glucose or fructose, or it can be considered a substitute. Parenteral administrations of galactose are therefore also possible with pure galactose or a solution in distilled water.

Composition of infusion solutions (g/L)

Component	Example																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
D-Galactose	50	5	60	40	30	15	10	5	2.5	25	20	25	10	30	20	25	30	45	45	50
L-Fucose	-	-	-	-	-	-	-	-	-	25	20	-	10	-	-	-	-	-	-	-
D-Mannose	-	-	-	-	-	-	-	-	-	-	-	25	10	-	-	-	-	15	10	-
D-Glucose	-	55	-	20	30	45	45	45	47.5	-	10	-	-	-	10	-	10	-	5	-
N-Acetylglucosamine	-		-	-	-	-	-	-	-	-	-	-	10	-	-	-	-	-	-	-
N-Acetylgalactosamine	-		-	-	-	-	-	-	-	-	-	-	10	-	-	25	-	-	-	-
D-Fructose	-		-	-	-	-	-	-	-	-	-	-	-	20	10	-	10*)	-	-	-
D-Lactulose	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10
Arginine	-	6	6	5	5	5	6	6	6	1	3	5	8	7	6	6	6	5	-	5
Phenylalanine	-	7	7	6	6	6	7	7	7	2	6	7	9	4	4	5	5	7	-	7
Valine	-	5	5	4	4	4	4	4	4	1	5	5	7	6	6	6	6	6	-	6
Leucine	-	7	7	7	7	7	7	7	7	2	7	7	9	7	7	8	8	8	-	8
Isoleucine	-	6	6	6	6	6	6	6	6	1	6	6	8	6	5	5	6	6	-	6
Lysine	-	7	7	6	6	6	7	7	7	2	7	6	9	7	7	6	6	7	-	7
Methionine	-	5	5	6	6	6	4	4	4	2	5	5	6	5	4	5	4	4	-	5
Histidine	-	-	-	-	-	-	-	-	-	-	-	-	5**)	-	-	-	2	1	-	-
γ-Globulin	-	5	3	7.5	7.5	7.5	9	10	10	-	-	-	-	8	7.5	5	5	7.5	8	7.5
Human albumin	-	5	5	6	6	-	-	-	7	-	-	-	-	10	10	10	-	-	-	-
Dextran	-	-	-	-	-	50	50	-	-	50	25	25	-	-	-	-	50	50	50	50
Poly(0.2-hydroxylethyl) starch	-	-	-	-	-	-	-	50	-	-	25	25	-	-	-	-	-	-	-	-
NaCl***	-	80	80	80	80	80	80	80	80	80	80	80	80	80	80	80	80	80	80	80
KCl	-	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
$CaCl_2$	-	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
$MgCl_2$	-	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

*) 5 g fructose + 5 g N-acetylmannosamine

**) + threonine (6), tryptophan (2.5)

***) In mval/L

Example 21

For the preparation of a syrup, one dissolves in 100 mL water: 40 g D-galactose, 8 g starch syrup DAB, preservative (such as, 60 mg methyl-4-hydroxybenzoate, 40 mg propyl-4-hydroxybenzoate, in each case sodium salt) and optionally additional vitamins, such as, retinol palmitate (27.5 mg), corresponding to 50,000 I.U. vitamin A, 0.25 mg Cholecalciferol®, corresponding to 10,000 I.U. vitamin D_3, 0.01 mg cyanocobalamin, 2 mg thiamine hydrochloride (vitamin B_1), 10 mg nicotinamide, 100 mg ascorbic acid (vitamin C), 1 mg DL-α-tocopherol (vitamin E), 40 mg orotic acid, and 300 mg calcium phospholactate. The syrup was administered to stressed patients according to a therapeutic regime.

Example 22

A 68-year old male patient with pronounced hepatic encephalopathy (liver coma) and severe impairments of consciousness received enterally 4 times daily one teaspoon of D-galactose (each approximately 6 g) in the tea. Within the first treatment day, the impairment of consciousness regressed almost completely. After interruption of the therapy, the impairment of consciousness resumed within one day, while a remission was observed after the readministration of galactose. The underlying disease was not eliminated by this treatment, but the serious symptom was alleviated to a considerable degree.

Example 23

A male patient who had diabetes mellitus for many years and had been undergoing insulin therapy (daily, approximately 75 I.U. human insulin) suffered partial loss of consciousness in conditions of severe hypoglycemia; after the onset of hypoglycemic symptoms (starting approximately at 65 mg% blood sugar value), he received 12 g galactose instead of the usual glucose administration. The hypoglycemic condition was completely eliminated after a few minutes. The effect of the galactose was twice as rapid as that of grape sugar and it could be administered without inducing strong reactions of counter control. The prophylactic galactose administration had the effect that the blood sugar level returned excellently to a normal level. The tendency to hypoglycemia was inhibited substantially, and without the patient falling into a hyperglycemic phase.

Example 24

In the animal test, Wistar rats with a body weight of approximately 250 g were treated with parenteral administrations of 100-800 mg D-galactose per kg body weight. The organs were removed after an ether narcosis, and the acid soluble supernatant of the organs was analyzed

after the removal of proteins to detect amino acids in an amino acid analyzer. The changes in the organ supply were detectable and reproducible.

Example 25

A 75-year old female patient with advanced Alzheimer's disease was treated with 5 teaspoons D-galactose daily. Her condition improved after a few days. The disease progress stopped almost entirely, from which it was concluded that the onset of Alzheimer's disease can at least be delayed substantially with galactose in case of early diagnosis and treatment.

Claims

1. Use of galactose for the parenteral nutrition and treatment of patients who require intensive care or are under metabolic stress, particularly in the postoperative phase, as well as for the treatment of liver diseases, absorption disorders, Alzheimer's disease, and stress situations in diabetes mellitus cases.

2. Use of galactose according to Claim 1 in the form of infusion and injection preparations for parenteral administration, based on monosaccharides which contain in addition optionally central amino acids, supplementing proteins, inorganic electrolytes and the usual dilution, pH regulation, stabilization and preservation additives, containing at least 5 wt% of the monosaccharide portion, which comprises at least 50 mol% galactose, and where the remainder consists of one of the following compounds: L-fucose, D-mannose, D-glucosamine, N-acetylgalactosamine, N-acetylmannosamine, and mixtures thereof.

3. Use of galactose according to Claim 2, where at least 10 wt% of the monosaccharide portion has the composition indicated in Claim 2.

4. Use of galactose according to Claim 2 or 3, characterized in that at least 20 wt% of the monosaccharide portion has the composition indicated in Claim 2.

5. Use of galactose according to one of Claims 2-4, characterized in that galactose and D-mannose are present in a molar ratio in a range from 200:1 to 2:1.

6. Use of galactose according to one of Claims 2-4, characterized in that galactose and D-glucosamine are present in a molar ratio in a range from 200:1 to 2:1.

7. Use of galactose according to one of Claims 2-4, characterized in that galactose and N-acetylmannosamine are present in a molar ratio in a range from 10:1 to 2:1.

8. Use of galactose according to one of Claims 2-4, characterized in that galactose and N-fucose are present in a molar ratio in a range from 200:1 to 2:1.

9. Use of galactose according to one of Claims 2-4, characterized in that galactose is the only monosaccharide.

10. Use of galactose according to one of Claims 1-9, in a glucose preparation having the usual composition in which 50-100% of the D-glucose is replaced with galactose.

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Translated by:

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TRANSLATIONS
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